

**REMARKS**

This paper is responsive to the restriction requirement mailed December 9, 2008 (“Restriction Requirement”). Claims 1-32 are currently pending in this application and are subject to a restriction requirement. There are no amendments and no new claims. Accordingly, Applicants respectfully submit that no new matter is added.

**Response to Restriction Requirement and Election of Species**

The Restriction Requirement sets forth the following allegedly distinct inventions:

- Group I:** Claims 1-23, 25-28, 30, and 32, drawn to a method of preventing and/or treating hearing loss comprising administration of formula (I) wherein neither R nor R' are cyclic and R<sub>1</sub> and R<sub>2</sub> do not form a heterocycle with the nitrogen to which they are attached;
- Group II:** Claims 1-23, 25-28, 30 and 32, drawn to a method of preventing and/or treating hearing loss comprising administration of formula (I) wherein R or R' are cyclic or R<sub>1</sub> and R<sub>2</sub> do form a heterocycle with the nitrogen to which they are attached;
- Group III:** Claims 24, 29, and 31, drawn to a product or medicament comprising a derivative of formula (I) wherein neither R nor R' are cyclic and R<sub>1</sub> and R<sub>2</sub> do not form a heterocycle with the nitrogen to which they are attached; and
- Group IV:** Claims 24, 29, and 31, drawn to a product or medicament comprising a derivative of formula (I) wherein R or R' are cyclic or R<sub>1</sub> and R<sub>2</sub> do form a heterocycle with the nitrogen to which they are attached.

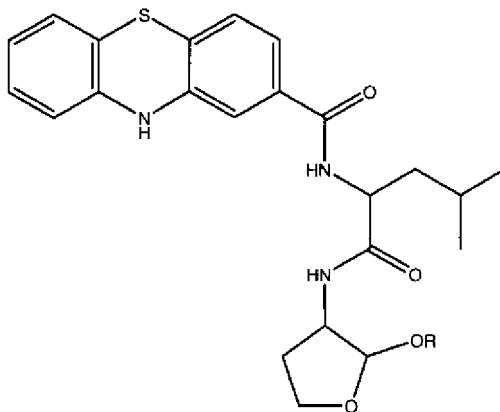
See Restriction Requirement at 2.

In order to be responsive to the restriction requirement, **Applicants hereby elect Group I, corresponding to claims 1-23, 25-28, 30 and 32, with traverse.**

The Restriction Requirement also requires Applicants to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. *Id.*, 3. The Restriction Requirement states that the “species are as follows: ... The heterocyclic derivative of formula(I) wherein R, R', R<sub>1</sub>, and R<sub>2</sub> are specified.” *Id.*, 3. The Restriction Requirement continues by stating that none of the claims correspond to the above species but that claims 1-23,

25-28, 30, and 32 are generic with respect to Groups I and II, and claims 24, 29, and 31 are generic with respect to groups III and IV. *Id.*, 3-4. The Restriction requirement alleges that the “species” do not relate to a single general inventive concept because they lack a special technical feature in view of WO 01/32654 which “teach[es] the compound N-[(1S)-1-([[(3S)-2-hydroxytetrahydro-3-furanyl]amino}carbonyl)-3-methylbutyl]-10H-phenothiazine-1-carboaximide, an embodiment of the claimed invention wherein R is H (pg 12, second from top).” *Id.*, 3-4.

In order to be responsive to the restriction requirement, Applicants hereby elect the following species:

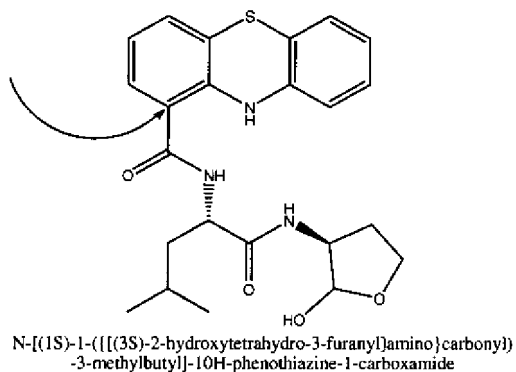


wherein R is H, alkyl, or -C(O)R'. If a more particular election is required, Applicants elect the species where R is -C(O)R' and wherein R' is a non-substituted alkyl.

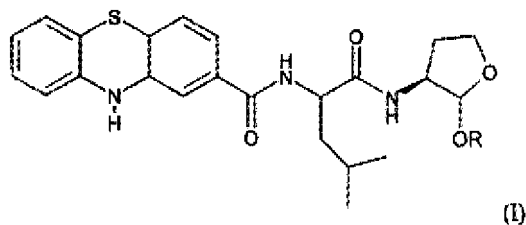
Claims 1-23, 25-28, 30, and 32 of Group I correspond to this elected species.

**Applicants respectfully traverse the restriction requirement for the following reasons.**

The Restriction Requirement states that the foreign reference WO 01/32654 “teach[es] the compound N-[(1S)-1-([[(3S)-2-hydroxytetrahydro-3-furanyl]amino}carbonyl)-3-methylbutyl]-10H-phenothiazine-1-carboaximide, an embodiment of the claimed invention wherein R is H (pg 12, second from top).” *Id.*, 2-3. The structure of this compound is provided below for reference:



As noted by the arrow, the amide linkage is substituted *ortho* to the amine in the heterocycle. In contrast, Applicants' claims provide that the amide linkage is substituted in the *meta* position, as shown below. See Claim 1.



Accordingly, the foreign reference does not disclose one of the special technical features of the presently claimed invention. Applicants respectfully request withdrawal of the restriction requirements.

Applicants also respectfully request rejoinder of any non-elected species in the event that a generic claim is found allowable. Applicants reserve the right to pursue any non-elected subject matter of the groups, if necessary, in one or more divisional or continuation applications.

**CONCLUSION**

In view of the above remarks, early notification of a favorable consideration is respectfully requested.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: January 9, 2009

By: /JEFF B. VOCKRODT/

Jeff B. Vockrodt  
Registration No. 54,833

Stefan M. Miller, Ph.D.  
Registration No. 57,623

Hunton & Williams LLP  
Intellectual Property Department  
1900 K Street, N.W., Suite 1200  
Washington, D.C. 20006-1109  
(202) 955-1500 (telephone)  
(202) 778-2201 (facsimile)